IN or OUT

METHOD OF TREATMENT

A PATENT PERSPECTIVE

PATENT[SM] WIRE
Where Inventions Live Long

METHOD OF TREATMENT

LIKE MANY OTHER FIELDS, MEDICAL DIAGNOSTICS AND HEALTHCARE HAS BEEN AN INTERESTING FIELD OF KNOWLEDGE SINCE INCEPTION OF HUMAN CIVILIZATION. TILL NOW, MILLIONS OF MEDICAL TOOLS HAVE BEEN DEVELOPED TO DIAGNOSE AND TREAT MYSTERIOUS DISEASES. HOWEVER, IT HAS BEEN AND WILL BE AN EVERLASTING EXERCISE, FOR, HUMAN HEALTH IS IN CONSTANT NEED OF IMPROVEMENT. FURTHER, REQUIREMENT OF NOVEL, EFFECTIVE AND ECONOMIC METHODS OF TREATMENTS SHALL GO ON AND ON.

SINCE METHOD OF TREATMENT DIRECTLY INTERFERES WITH HUMAN/ANIMAL LIFE, THE LAW MAKERS HAVE TAKEN SPECIAL PRECAUTION TO PREVENT EXCLUSIVITY OVER THE COMMERCIAL USE OF THESE INVENTIONS. EXCEPT US, AUSTRALIA AND NEW ZEALAND, THE METHOD OF TREATMENT IS GENERALLY EXCLUDED FROM PATENT PROTECTION. IN INDIAN CONTEXT TOO, SECTION 3(I) OF THE INDIAN PATENT ACT, 1970 CONTAINS THE EXCLUSION OF METHOD OF TREATMENT FROM PATENT PROTECTION. SECTION 3(I) OF THE INDIAN PATENT ACT, 1970 READS AS:

> "any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."

However, the Indian Patent Act, 1970 does not prevent the patenting of products that have medical applications, like pharmaceuticals or medical devices such as scalpels, staplers, surgical sutures, and stents and diagnostic kits.

Although there are numerous factors involved in deciding fate of a Patent Application, the stakeholders are keen on interpreting exclusion clauses in numerous ways. It is true that there cannot be a single interpretation of a particular law, however, the basic instinct of the law or clause in particular can always be a subject matter of fair discussion under various circumstances. One thing should always be kept in mind that it is the welfare of public at large which must prevail in decisions pertaining to fields purely relating to human health!

INTERPRETATION ON NON PATENTABILITY

Section 3(i) of the Patent Act, 1970 represents restriction clause where "method for treatment of the human or animal body by surgery or therapy or medicinally and diagnostic and therapeutic method practiced on the human or animal body to render them free of disease or to increase their economic value or that of their products" are not eligible for an exclusive right.

1.'METHOD FOR TREATMENT BY SURGERY' MEANS:

a) Methods for surgical treatment (such as incision, excision, centesis, injection or implant);
b) Methods of using, inserting, moving, maintaining, operating and extracting a medical device (such as Catheter, endoscope) inside the human body (excluding inside the mouth, inside the external nostril, and inside the external ear canal);
c) Preparatory treatment for surgery (such as anesthesia procedures for surgery or method of disinfecting skin before injection/incision);
d) Cosmetic methods that include surgical operations whose purpose is not therapeutic or diagnostic are also considered as "methods for treatment of the human body by surgery practiced on the human body."

2. 'METHOD FOR TREATMENT BY THERAPY' MEANS:

a) Methods of administrating medicine or giving physical treatment to a patient for curing or restraining a disease;
b) Methods of preventing a disease (such as methods of preventing tooth decay or influenza);
c) Methods of maintenance of physical health (like methods of massage or Yoga or Pranayaam) are also considered to be methods of preventing
d) Preparatory treatment for therapy (such as method for arranging electrodes for the electrical therapy), supplemental methods for improving treatment effects (viz. rehabilitation methods), or methods for nursing associated with the treatment (viz. methods to prevent bedsores)

3. 'METHOD FOR CURATIVE AND PROPHYLACTIC TREATMENT' MEANS:

Therapy relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as easing of the symptoms of pain and suffering. It is established in case laws that a prophylactic treatment, aimed at maintaining health by preventing ill effects that would otherwise arise, amounts to a method for treatment by therapy.

Both prophylactic and curative methods of treating disease are covered by the word therapy, since both are directed to the maintenance or restoration of health.

4. 'METHOD FOR TREATMENT BY MEDICINE' MEANS:

a) Methods of giving special form [viz. film, tablet, capsule, syrup) of medicine for the treatment of a patient;
b) Methods of giving medicine at definite time interval for curing or restraining a disease;
c) Methods of mixing two or more forms of medicine for the treatment of a patient;
d) Doses form of a medicine;
e) Different modes of providing medicine (viz. oral, intramuscular, intravenous, etc).

5. 'DIAGONSTIC METHOD' MEANS:

a) Methods of judging (excluding judgment by a device) for the medical purpose the physical condition of a human body such as diseases and physical health, the mental condition of a human body, or prescription or treatment/surgery plans based on these conditions.
b) Methods of judging whether the patient has had any complication by observing the test result or imaging.

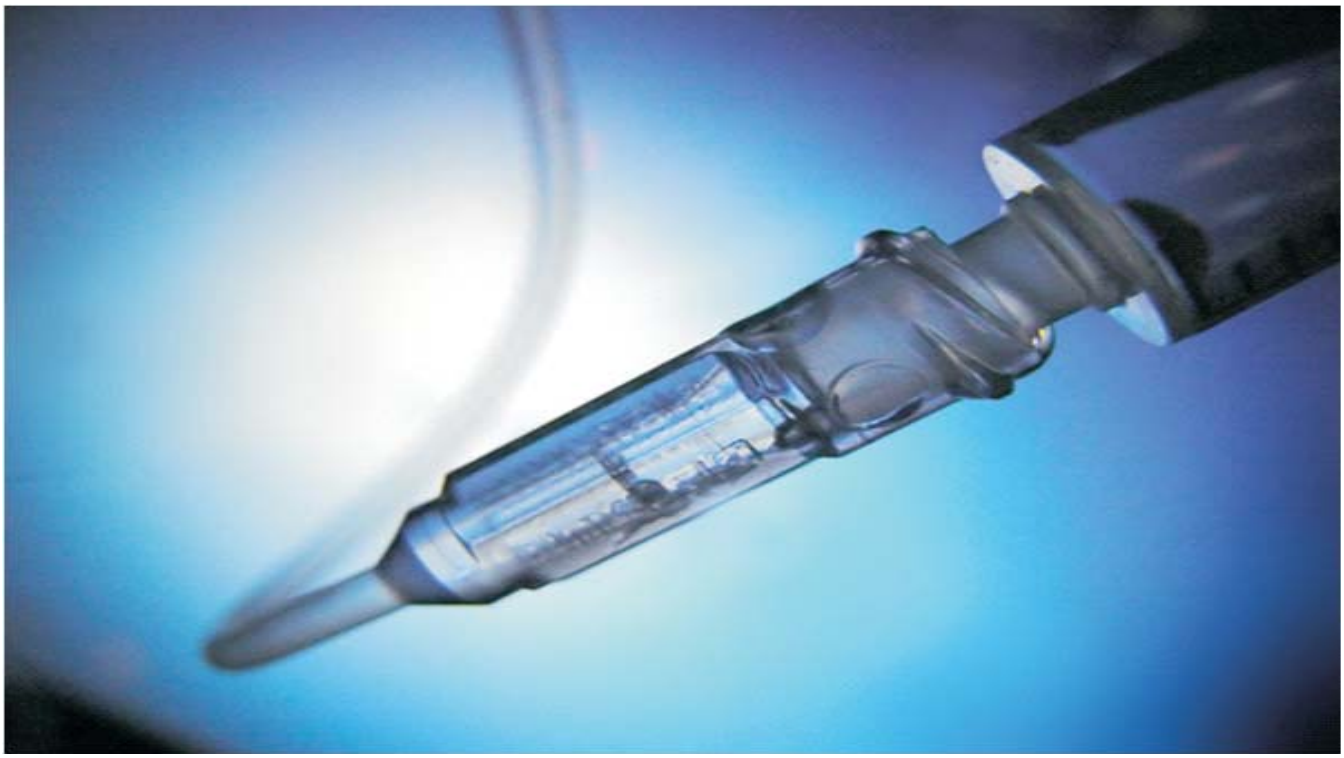
WHAT IS OUT [NON PATENTABLE]

The following procedures are considered as method for treatment and hence not patentable:

1. A method for treating an affected part during operation.
2. A method for sampling body fluid.
3. A method for the observation of the internal body part by using an endoscope.
4. A method for Gene therapy.
5. A method for treating cancer or diabetes.
6. A method for regenerating blood cells.
7. A method for giving electrical stimulus by a pacemaker.
8. A method for retinal stimulation using an artificial eye system.
9. A method for X-ray irradiation.
10. A method for blood purification.
11. A method for measuring hematocrit values of blood.
12. Treatment of sheep for increasing wool.

INTERPRETATION ON PATENTABILITY

Section 3(i) of the Patent Act, 1970 does not mention any 'product' for the medical, surgical, curative, prophylactic, diagnostic, and therapeutic use for the treatment of human or animal body. Therefore, patent law includes medico-physical devices for use in therapy and surgery, as well as to pharmaceuticals and diagnostic kits. When such devices are novel, their patentability is generally not affected by the prohibition on patenting method of treatment. The device and pharmaceuticals can normally be claimed as such, using a standard product claim format.



WHAT IS IN [PATENTABLE]

The following procedures are not classified as method for treatment and hence can be considered as patentable:

1. A medical device or a medicinal substance is a product, and is not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human or animal body”.
2. A method for controlling the operation of a medical device.
3. Measuring structures and functions of the various organs of the human body, is not considered to be diagnostic methods practiced on the human body.
4. Methods of extracting samples and data from the human body, or methods of analyzing e.g., comparing such samples and data with standards.
5. Preparatory treatment for measuring structures or functions of various organs of the human body.
6. Diagnostic kits or ELISA kits for sampling and identifying disease.
7. Methods for treating samples that have been extracted from the human body.
8. A method for manufacturing a medicinal product (e.g., blood preparation, vaccine, genetically modified preparation) by utilizing raw material collected from a human being.
9. A method of analyzing a medicinal product or a medical material, or intermediate product thereof which is manufactured by utilizing raw material collected from a human being.

10. A method for manufacturing a medical material (e.g., an artificial substitute or alternative for a part of the human body, such as an artificial bone, a cultured skin sheet, etc.) by utilizing raw material collected from a human being.

11. A method of manufacturing an intermediate product for a medicinal product or a medical material (e.g. methods for differentiation and induction of the cells, methods for separation and purification of the cells) by utilizing raw material collected from a human being.

IN AND OUT [LANGUAGE OF CLAIMS]

MANY A TIMES THE CONSTRUCTION OF CLAIMS DECIDES THE FATE OF IN AND OUT FOR PATENT PROTECTION. CLAIM(S) ARE THUS RIGHTLY CONSIDERED AS THE HEART OF A PATENT. THEREFORE, EVERY WORD COUNTS AND DECIDES THE PATENTABILITY OF DISCLOSED INVENTION.

This will be more clarified with the help of few examples:

EXAMPLE: 1

"A method for the treatment of cancer in a patient comprising administering to said patient an effective amount of siramesine or a pharmaceutically acceptable salt thereof, wherein the cancer is selected from the group consisting of fibrosarcoma, breast cancer, neuroblastoma, prostate cancer and cervical cancer".

(The invention to be considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" as the invention proposes a process)

The method is to execute administration of an effective amount of an anticancer agent in cancer patient for treatment and hence falls under "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

"A pharmaceutical composition comprising siramesine or a pharmaceutically acceptable salt thereof for the treatment of cancer in a patient, wherein the cancer is selected from the group consisting of fibrosarcoma, breast cancer, neuroblastoma, prostate cancer and cervical cancer".

(The invention not to be considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" as the invention now proposes a 'product' and not a process)

The claimed treatment of cancer is an invention of a pharmaceutical composition comprising siramesine or a pharmaceutically acceptable salt thereof; hence it is a product invention. Therefore, it is not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

EXAMPLE: 2

"A method of detecting the presence of a regeneration initiation cell in a sample comprising: a) isolating low density mononuclear cells from the sample; b) transplanting the low density mononuclear cells into a recipient animal with tissue or organ damage; and c) determining whether or not the transplanted cells engraft the damage tissue or organ, wherein engraftment of the damaged tissue or organ indicates the presence of regeneration initiation cells in the sample".

(The invention is to be considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

The claimed invention is a method for detecting the presence of a regeneration initiation cell into a recipient animal with tissue or organ damage and thus a method for diagnosis of the human body. Also the claimed invention is a method for transplanting the low density mononuclear cells into the body and thus a method for treatment of the human body by surgery. Therefore, the claimed invention is a "method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

"A pharmaceutical composition for treating or preventing pancreatic damage comprising regeneration initiating cells in admixture with a pharmaceutically acceptable diluent, excipient or carrier, wherein the regeneration initiating cells are present in an effective amount to treat or prevent pancreatic damage".

(The invention not to be considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")

As the regeneration initiating cells for treatment of damage pancreatic cells described in the claim itself is a product, it does not fall under "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

However, it should be noted that the exclusion from 'diagnostic, therapeutic and surgical methods for the treatment cannot be avoided merely by drafting claims that omit one or more of the steps of such method. Those steps are in fact essential essence for properly carrying out the invention and must be disclosed in the specification.

IN AND OUT [JURISDICTIONS]

Patent is a territorial right in nature. Therefore, same or substantially same invention must be filed in different jurisdictions to secure the patent right, that too within a prescribed time period. However, it is seldom strategized during the pre-filing stages that construction of claims is done according to the different jurisdictions and different laws. It should be noted that the method of treatment clause is not ubiquitous in nature. Therefore, construction of claims can be modified/amended/included while entering into a particular jurisdiction. The status of method of treatment clause is listed below:

JURISDICTION	CLAUSE	STATUS
INDIA	SECTION 3(I)	NOT ALLOWED
EUROPEAN UNION	ARTICLE 53(C) & 52(4)	NOT ALLOWED
USA	CLASS 128, 239, 897 & 899	ALLOWED
JAPAN	ARTICLE 29(1)	NOT ALLOWED
CHINA	ARTICLE 25.1(3)	NOT ALLOWED
EGYPT	ARTICLE 2	NOT ALLOWED
KOREA	ARTICLE 32	NOT ALLOWED
NEW ZEALAND	SECTION 2(1)	ALLOWED FOR NON HUMAN
PAKISTAN	SECTION 7(4)(C)	NOT ALLOWED
SOUTH AFRICA	SECTION 25(A)	NOT ALLOWED
THAILAND	SECTION 9(4)	NOT ALLOWED
AUSTRALIA	SECTION 18(1)(A)	ALLOWED
CANADA	SECTION 2	NOT ALLOWED
SINGAPORE	SECTION 16(2)(2)	NOT ALLOWED

Article 27(3)(a) of the TRIPS Agreement permits its members to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability. By virtue of this, almost every member country except US, Australia and New Zealand has excluded the methods for treatment from patentability scope.

IN AND OUT [PATENT OFFICES' DECISION]

Article 53(c) EPC and the Manual of Indian Patent Practice and Procedure specify a number of exceptions to patentability in the field of 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. However, in any case, an independent claim ought to include all the essential features needed to define the invention. If the application as originally filed makes it clear that a method is the key 'essence' of the invention, the same will not be accepted by the patent office merely by amending the claims that omit one or more steps of such method claim.

In decision 3044/CHENP/2006, the claims as originally filed were directed towards treating warts with tellurium compounds. The Applicant amended the claims to include pharmaceutical composition during the examination phase. However, the essence of invention (read as specification) did not describe that tellurium-containing compound [product claimed] is able to treat the huge variety of diseases claimed. The Patent office did not allow this invention on the basis of 2(1)(j), 3(e) and 3(i).

In decision 7831/DELNP/2006, the claims filed were directed towards a combination composition containing Ibuprofen and Paracetamol (known drugs). The controller noted that the fixing of doses for treatment of patient are treated as a method of treatment under section 3(i) of the Act and it is part of medical practitioner prerogative as it is his assessment of the patient's age, state of condition, health etc. by which practitioner decides quantum and frequency of doses. Therefore, dosage claims here fall under the method claim which is not allowed under section 3(i) of the Act.

In Decision T74/93 the Enlarged Board had to decide whether a claim directed to the use of a contraceptive composition for applying to the cervix of a female mammal capable of conception is excluded from patentability by Article 52(4) EPC. The Board noted that methods of contraception are not excluded per se from patentability as stipulated in Article 52(4), first sentence, EPC, since pregnancy is not an illness and therefore its prevention is not a general therapy according to Article 52(4) EPC.

Some diagnostic methods incorporate procedures that involve an invasive interaction with the human body, for example taking a blood sample or administration of a substance by injection. The Enlarged Board indicated in their decision G1/07 that invasive method steps representing a substantial physical intervention on the body which require professional medical expertise to be carried out and which entail a health risk, even when carried out using such expertise, will be excluded from patentability under Article 53(c) EPC as being surgical steps.

In decision T 383/03 the board indicated that if a method involving a physical intervention on the human or animal body (treatment by surgery) is clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal, then the method does not fall under the exclusion from patentability provided for in Article 52(4) EPC.

IN AND OUT [UNDER SECTION 3(I) IN 2013]

In 2013, the Indian Patent Office decided a total of 1695 patent cases. Out of these 62% were granted, and 34% were refused. Under section 3(i), 42 patent applications have been scrutinized. Out of these 31 were granted and 11 were rejected.

GRANTED

IN/PCT/2002/00573/MUM	1901/MUMNP/2009	3336/CHENP/2006	893/CAL/1998
228/MUMNP/2010	5934/DELNP/2005	5707/DELNP/2006	290/DELNP/2006
558/MUMNP/2007	696/KOL/2007	2520/CHENP/2004	5289/DELNP/2006
1393/MUMNP/2009	7765/DELNP/2007	72/CHE/2007	3411/DELNP/2006
2053/MUMNP/2008	5536/DELNP/2006	4608/CHENP/2006	3341/DELNP/2006
3102/DELNP/2007	670/DEL/2004	2246/DELNP/2007	4678/CHENP/2006
6774/DELNP/2006	1011/MUM/2008	1906/MUMNP/2007	4401/CHENP/2006
488/CHE/2007	1504/CHE/2005	7641/DELNP/2006	

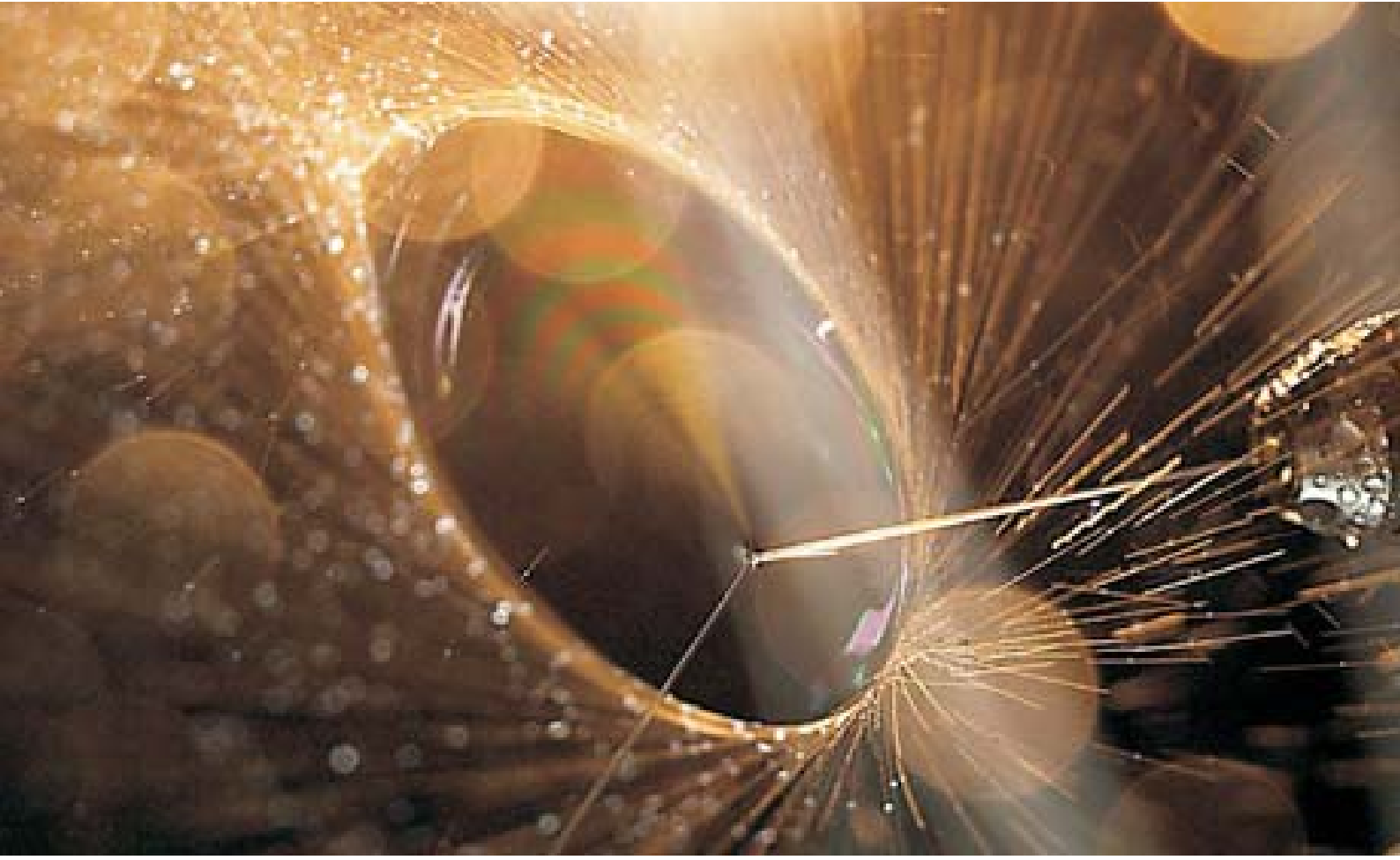
REFUSED

3824/DELNP/2004	2582/DELNP/2006	314/KOL/2006	2335/DEL/2005
1521/MUMNP/2006	1193/DELNP/2003	7831/DELNP/2006	1729/KOLNP/2005
1537/KOLNP/2006	3371/KOLNP/2007	3044/CHENP/2006	

Since patent is a territorial right, the decision of refusal or grant is purely based on the territorial law and their practices. However, territorial patent practices within the purview of specific clause play a major role while deciding the refusal or grant of a patent. In this scenario, it is possible that same patent [family patent] may not be refused or granted in other jurisdiction having the similar clauses.

IN AND OUT [FAMILY PATENT]

APPLICATION NO.	REFUSED	GRANTED
2582/DELNP/2006	India	Australia, Europe, New Zealand, Korea, Mexico
314/KOL/2006	India	China
2335/DEL/2005	India	EPO, UK
1193/DELNP/2003	India, Russia	EPO, Korea
7831/DELNP/2006	India	EPO, UK, Korea, Canada, Australia
1537/KOLNP/2006	India	EPO, Korea, Australia, Canada
3371/KOLNP/2007	India	EPO, US, Australia, Canada, Mexico



CONCLUSION

Many a times, refusal and grant depends on the interpretation of language of claims by the Patent Examiners or Agents, apart from other procedural and patentability aspects. To avoid this situation, if a claimed process does constitute a method claim, it is always advisable to draft a use-limited product claim directed to a new substance or composition for use in the specified diagnostic method. It is further noticeable fact that maximum percentage of refused patent applications filed in India or EPO are claiming priority from US applications. Presently, at the time of initial filing, it is seldom practiced to include description suitable for foreign jurisdictions. A specification is drafted keeping in mind the jurisdiction where the application originates. However, it is highly recommended to consider providing description in a manner so that later stage amendments are not rejected outright for the want of lack of information in description. Thus for a 'method of treatment' class of inventions, the product oriented description should also be considered and included with due care towards other concerns [like unity of invention]. The inclusion should be in a manner so as to support future amendments.

As the discussion shows, although methods of treatment of the living animal and human body are excluded from patent protection there are fairly many options for getting useful patent protection in this important field.

Authors

Mr. Lalit Ambastha
Founder, Patentwire Consultants Pvt. Ltd.
Email: lalit.ambastha@patentwire.co.in

Ms. Shruti Kaushik
Director, Patentwire Consultants Pvt. Ltd.
Email: k.shruti@patentwire.co.in

Patentwire Consultants Pvt. Ltd.
B-10, Ground Floor, Vishwakarma Colony
M.B. Road, New Delhi-110044
India

Tel: +91-11-26360036
Fax: +91-11-26360037
Email: desk@patentwire.co.in

www.patentwire.co.in

Sources:

The Indian Patents Act, 1970
Manual of Patent Practices
European Patent Manual
Indian Patent Databases
Japanese Patent Office
European Patent Office

Disclaimer

Patentwire has used reasonable endeavours to ensure that contents of this report were correct at the time the relevant pages were created, modified and published. Patentwire does not make any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefullness of any information. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the Patentwire. The views and opinions of authors expressed herein do not necessarily state or reflect those of the Patentwire.

Copyright

Unless otherwise stated, the copyright or similar right of this report is owned by Patentwire Consultants Pvt. Ltd. You are permitted to print or download this report for your personal use only. None of this material may be used for any commercial or public use. The name and logo of Patentwire are trademarks of Patentwire Consultants Pvt. Ltd. You are not permitted to use or reproduce or allow anyone to use or reproduce these trademarks for any reason. Other company, product, pictures and service names may be trademarks or service marks or copyright of others.